IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

UNITED STATES OF AMERICA and THE STATE OF TENNESSEE *ex rel.* SUZANNE ALT *et al.*,	)	
Plaintiffs,	)	
	)	**Case No. 3:16-cv-0549**
v.	)	**Judge Aleta A. Trauger**
ANESTHESIA SERVICES ASSOCIATES, PLLC, d/b/a COMPREHENSIVE PAIN SPECIALISTS, *et al.*,	)	
Defendants.	)	

MEMORANDUM

The United States of America and the State of Tennessee (collectively, "the government" or "plaintiffs") bring this action under the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*; the Tennessee Medicaid False Claims Act ("TMFCA"), Tenn. Code Ann. §§ 71-5-182 to -185; the Federal Priority Statute, 31 U.S.C. § 3713; and common law theories of payment by mistake, unjust enrichment and fraud, against defendants Anesthesia Services Associates, PLLC d/b/a Comprehensive Pain Specialists ("CPS"), Peter B. Kroll, M.D., John Davis, Steven R. Dickerson, M.D., Gilberto A. Carrero, M.D., and Russell S. Smith, D.C. (*See* Consol. Compl. in Intervention, Doc. No. 65.) Now before the court is the Partial Motion to Dismiss the Consolidated Complaint in Intervention filed by defendant Peter Kroll, M.D. (Doc. No. 96.)

Kroll seeks the partial dismissal of four of seven claims for relief asserted against him in the government's Consolidated Complaint. The plaintiffs filed a Joint Memorandum in Opposition to the Partial Motion to Dismiss (Doc. No. 113), and Kroll has filed a Reply (Doc. No. 116). For

the reasons set forth herein, Kroll's motion will be denied.

I. STATUTORY AND REGULATORY FRAMEWORK

This case involves the defendants' submission of requests for reimbursement for medical services from a number of different federal and state health care programs (collectively, "Government Health Care Programs"), including Medicare, Medicaid/TennCare, TRICARE, and CHAMPVA/Choice. (Consol. Compl., Doc. No. 65 ¶ 3.) For purposes of the Motion to Dismiss, the parties focus primarily on the requirements of Medicare, so the court does as well.[1]

As relevant here, Medicare is a federal health insurance program for the elderly and people with disabilities. *See* 42 U.S.C. § 1395c. Medicare Part B, which provides outpatient coverage for, among other things, diagnostic laboratory tests (*see* 42 C.F.R. § 410.32), only covers medical services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). "[Laboratory t]ests that are performed in the absence of signs, symptoms, complaints, personal

[1] TRICARE is a government health care program administered by the Defense Health Agency ("DHA"), a division of the Department of Defense. TRICARE provides health care insurance for active duty military personnel, military retirees, and military dependents. (Doc. No. 65 ¶ 43.)

The Veterans Administration provides, and pays for, inpatient and outpatient health care services for veterans and their dependents and survivors through the Veterans Health Administration ("VHA") and the Civilian Health and Medical Program for the VA ("CHAMPVA"). (Doc. No. 65 ¶ 51.) Through the Veterans Access, Choice, and Accountability Act of 2014 ("VACAA"), veterans may enroll in the Veterans Choice Program ("Choice"), which provides primary care, inpatient and outpatient specialty care, and mental health care for eligible veterans when the local VA health care facility cannot provide the services for certain specified reasons, such as lack of available specialists, long wait times, or extraordinary distance from the veteran's home. (Doc. No. 65 ¶ 52.)

The Medicaid program provides federal funding for medical and health-related services for certain individuals and families with low income and limited financial resources. (*Id.* ¶ 47.) The Medicaid program is a joint federal-state health care program. Through its TennCare program, Tennessee participates in the Medicaid program pursuant to Tenn. Code Ann. §§ 71-5-101 through -199.

history of disease, or injury are not covered except when there is a statutory provision that explicitly covers tests for screening as described." Medicare Claims Processing Manual: Chapter 16—Laboratory Services § 120.1, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104C16.pdf (last visited December 17, 2019).

Medicare establishes its national payment policy for covered items or services through national coverage determinations ("NCDs"), which are formal decisions by the Secretary of the Department of Health and Human Services ("HHS") regarding whether, and under what circumstances, Medicare covers a particular item or service. *See* 42 U.S.C. § 1395ff(1); 42 C.F.R. § 405.1060(a). NCDs are binding on both Medicare contractors and administrative law judges, who preside over Medicare coverage appeals. *See* 42 U.S.C. § 1395ff(1)(A)(i); 42 C.F.R § 405.1060(a). Medicare Administrative Contractors ("MACs") act as agents for the government in reviewing and paying claims submitted by health care providers. *See* 42 U.S.C. § 1395h; 42 C.F.R. §§ 421.3, 421.100. MACs process and pay Medicare claims within a specified jurisdiction on behalf of the Centers for Medicare and Medicaid Services ("CMS") and have authority to issue local coverage determinations ("LCDs") for that jurisdiction. *See* 42 U.S.C. § 1395ff(f)(2); *see also id.* § 1395m-1(g) (noting that Medicare contractors may issue LCDs regarding clinical diagnostic laboratory tests under the same process). LCDs, like NCDs, govern Medicare coverage for a particular item or service. *See id.* § 1395ff(f)(2)(b). In adjudicating coverage appeals, administrative law judges "give substantial deference" to local coverage determinations, but they are not bound by them. 42 C.F.R. § 405.1062.

An entity seeking reimbursement for services provided to Medicare patients must submit a CMS Form 1500, or its electronic equivalent, to the appropriate MAC. *See United States ex rel. Hobbs v. MedQuest Assocs.*, 711 F.3d 707, 711 (6th Cir. 2013). "The[CMS–1500] form[]

reflect[s] the treatment or services provided and identif[ies] the [entity that] provided them. Tests, supplies, and services are correlated to a series of unique numbers, called CPT codes, which quickly convey to the [claims processor] what reimbursable expenses the [entity] has incurred." *Id.* The CMS Form 1500 requires the entity to certify that "the services on this form were medically necessary." Health Insurance Claim Form (Form 1500) at 2, available at https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf (last visited December 17, 2019).

The FCA specifically provides for civil liability and damages for, *inter alia*, knowingly presenting, or causing to be presented, false or fraudulent claims for payment to the United States and for knowingly making or using false records or statements material to false or fraudulent claims paid by the United States. 31 U.S.C. §§ 3729(a)(1), (2). The Tennessee Medicaid False Claims Act effectively mirrors the language of the FCA, providing civil liability and damages for false claims for payment under the state Medicaid program (TennCare). Tenn. Code Ann. § 71-5-182(a)(1).

II. FACTUAL AND PROCEDURAL BACKGROUND[2]

The first *qui tam* complaint against CPS alleging violations of the FCA was filed under seal in this court on March 9, 2016, entitled *United States ex rel. Alt v. Anesthesia Services Associates, PLLC*, No. 3:16-cv-00549. (Doc. No. 1.) Five other *qui tam* actions were brought against CPS and other defendants, alleging additional FCA violations, all of which were filed in, or transferred to, this district. In response to the *qui tam* complaints, the United States and Tennessee conducted an investigation into CPS and its medical providers. The court granted an unopposed motion to consolidate five of the actions on April 15, 2019; the sixth was voluntarily

[2] The factual allegations are drawn from the Consolidated Complaint. (Doc. No. 65.)

dismissed. (Doc. No. 42.) On April 22, 2019, the United States and the State of Tennessee filed notices of their intent to intervene in part and to decline to intervene in part in the consolidated action. They filed their Consolidated Complaint on July 22, 2019. (Doc. No. 65.)

The Consolidated Complaint alleges that CPS, a Tennessee professional limited liability company with its principal place of business in Franklin, Tennessee, began operations in 2000. Although the initial focus of the practice was anesthesia, by 2011, it was operating over sixty pain management clinics across twelve states and employed approximately 250 health care providers, who saw approximately 48,000 patients per month. The principal physician-owners of CPS were defendants Dickerson, Carrero, and Kroll ("Owners"). (*Id.* ¶ 23.)

Kroll is a medical doctor certified in anesthesiology and pain medicine. He took an ownership interest in CPS and began treating patients at CPS in August 2006. He served on the Board of Directors at all relevant times, was Chairman and President of the Board beginning on September 30, 2015, and served as Chief Medical Director from January 2016 until the company ceased operating. (*Id.* ¶ 27.) In his managerial role, Kroll was responsible for developing and approving CPS's policies. (*Id.* ¶¶ 127, 132, 140, 158, 169, 335.) The company's Chief Executive Officer, defendant Davis, had the authority to oversee the day-to-day operations of the company from May 2011 until June 2, 2017. (*Id.* ¶ 25.) In July 2018, CPS began dissolution proceedings and sold off its assets. It is no longer in business. (*Id.* ¶ 23.)

CPS began operating its own testing facility in July 2012 and its own pharmacy in September 2013. (Doc. No. 65 ¶¶ 82, 83.) In 2015, CPS opened a larger test facility in Brentwood, Tennessee, that focused on urine drug screening (or testing) ("UDS" or "UDT"), pharmacogenetic testing, and hormone panels, among other laboratory tests. (Doc. No. 65 ¶ 87.)

While CPS was in operation, Kroll and the other Owners submitted requests for

reimbursement for medical services from the Government Health Care Programs. (*Id.* ¶ 3.) Beginning in 2011 through the dissolution of the company, Kroll and other CPS providers submitted thousands of claims for medical tests that, according to the government, were medically unnecessary, including UDT, specimen validity testing (defined as "analy[sis of] a urine specimen to ensure that it is consistent with normal human urine and has not been adulterated or tampered with" (*id.* ¶ 118), and psychological testing. Kroll and other CPS providers also billed for acupuncture, a non-covered service, and then refused to refund the overpayment even after CPS brought this improper billing to their attention. (*Id.* ¶¶ 3, 4, 6, 10.) The government also alleges that Kroll submitted over 2,500 claims to Medicare, for which CPS was paid almost $350,000, falsely claiming that he was the "Rendering Provider" when, in fact, he was out of the country on vacation. (*Id.* ¶ 11.)

As it expanded and hired new personnel, CPS entered into a variety of compensation packages with its physicians. Typically, physicians received between fifty and sixty percent of their net revenues, with bonuses based on contributions to a pool of revenue for self-referrals for UDT, genetic and other blood testing, DME, and iPad psychiatric tests. (*Id.* ¶ 90.) The Owners, including Kroll, were compensated at 100 percent of their net revenues plus a percentage from the pool of ancillary services revenues to which CPS providers contributed. (*Id.* ¶ 92.)

As a matter of policy, CPS "ensured that its providers ordered at least six urine tests on every patient, pharmacogenetic blood tests, Health and Wellness panels, and iPad tests purportedly to measure depression and suicidal thoughts, and ancillary services whenever possible." (*Id.* ¶ 95.) The crux of the Consolidated Complaint is that CPS defrauded the Government Health Care Programs through billing for non-reimbursable and/or medically unnecessary UDT, blood testing for genetic risk factors, and psychological testing using iPads. (*Id.* ¶ 97.)

Urine Drug Testing

The government concedes that urine drug testing is a necessary and appropriate tool, under certain circumstances, for monitoring the treatment of pain patients, specifically to verify whether pain patients, especially those taking opioid medications, are compliant with their prescriptions and are not taking other drugs that could interfere with their treatment or pose a risk of overdose. (Doc. No. 65 ¶ 98–99.) When UDT is medically necessary, the Government Health Care Programs provide reimbursement for it. The government asserts, however, that the defendants misused UDT as a means to "bilk the United States and Tennessee out of millions of dollars." (*Id.* ¶ 99.)

The government alleges that it is common practice in the medical community to first order a "qualitative test" of urine to detect the presence or absence of a wide spectrum of drugs or drug metabolites. Qualitative testing does not measure the concentration of any particular drug. (*Id.* ¶ 100.) For patients deemed at high risk for the potential to abuse drugs, or if the provider suspects that a patient may have drugs in his system, the medical community recommends on-site, or point of care ("POC"), testing to obtain immediate results of qualitative testing. POC testing is reimbursed at a lower rate than off-site testing. (*Id.* ¶ 101.)

Depending upon the results of the qualitative testing, it may be medically appropriate to perform a "quantitative" drug test to determine the concentration of a specific drug (or drugs) in the patient's system. The purpose of quantitative testing is to confirm any unexpected positive results from the qualitative testing and to determine how much of a specific substance is in the patient's system. Unlike a qualitative test, which can test for a broad spectrum of substances in the sample at once, quantitative testing requires a separate test for each specific drug the concentration of which is sought. The testing equipment is more sophisticated, and the tests cost more and are reimbursed at a higher rate than qualitative testing. (*Id.* ¶ 102.)

The Consolidated Complaint alleges that (unspecified) Medicare rules limit quantitative testing, "in most cases," to situations in which qualitative testing has already been performed *and* the results indicate that quantitative testing for specific substances is needed. Thus, the Government Health Care Programs generally require providers to make the decision to conduct quantitative testing on a case-by-case basis. (*Id.* ¶¶ 103, 104.) Many MACs expressly "require providers to assess patient risk on an individualized basis to determine the appropriate frequency of testing" and, for quantitative testing, which substances to test for. (*Id.* ¶ 105.)

From 2011 to February 25, 2018, Cahaba Government Benefit Administrators, LLC ("Cahaba") was the MAC that administered Medicare Part B claims in Tennessee. Cahaba issued a local coverage determination ("LCD") in October 2015, entitled "Pathology and Laboratory: Qualitative Drug Testing," which stated that qualitative testing "may be followed by confirmation with a second method, only if there is a positive or negative finding inconsistent with the setting of a symptomatic patient." (*Id.* ¶ 107 (quoting LCD L34501).) Cahaba further notified providers that "[r]outine 'per visit' drug testing in chronic pain patients is noncovered," meaning, according to the government, that providers are not authorized to use a standing order that authorizes the same set of tests for every patient. (*Id.*)

In June 2015, Cahaba notified providers that LCD L35920, entitled "Pathology and Laboratory: Quantitative Drug Testing," would go into effect on October 1, 2015. This LCD expressly stated:

> [P]hysician-directed definitive profile testing is reasonable and necessary when ordered for a particular patient based upon historical use and community trends. However, the same physician-defined profile is not reasonable and necessary for every patient in a physician's practice. Definitive UDT orders should be individualized based on clinical history and risk assessment, and must be documented in the medical record. Some labs offer comprehensive definitive drug testing panel ("CDDP") of 40 or more drugs. It is not reasonable and necessary to bill individual billing codes for this comprehensive testing.

. . . .

> Routine standing orders for all patients in a physician's practice are not reasonable and necessary. Physician-defined standing orders for pre-determined drug panels according to specific patient profiles for a limited sequential period may be reasonable and necessary and must be documented in the patient's medical record."

(*Id.* ¶¶ 108–09.)

In addition, Cahaba defined "[s]pecimen validity testing, including, but not limited to, pH, specific gravity, oxidants, creatinine," as a non-covered service. (*Id.* ¶ 110.) As indicated above, specimen validity testing essentially tests whether a urine sample is actually a valid sample. (*See supra*, page 6, citing Doc. No. 65 ¶ 118.) HHS has indicated that, "when used for the purpose of determining whether a specimen is adulterated," specimen validity testing is "not being used to manage a beneficiary's specific medical problem" and, therefore, is not covered by Medicare. (Doc. No. 65 ¶ 118 (quoting Medicare Improperly Paid Providers for Specimen Validity Tests Billed in Combination with Urine Drug Tests, HHS-OIG Pub. A-09-16-02034, February 2018).)

Beginning in 2011, well before Cahaba issued the LCDs regarding UDT in 2015, the Owners increased the amount of UDT being performed on their patients in order to obtain more money from the Government Health Care Programs. Specifically, in September 2011, John Davis notified PhyData, CPS's third-party billing company at the time, by email that it should "bill as 12 units every time" for UDTs on the Owners' patients, including Kroll's. (*Id.* ¶¶ 121–22.) The Owners were aware of this policy, because they were copied on the email, which was referenced as "VERY URGENT: UDS 80101." (*Id.* ¶ 122.)

In addition, by opening its own testing facility in 2012, CPS was able to recover even more revenue relating to testing. (*Id.* ¶¶ 123–24.) Beginning no later than October 2013, CPS required its providers to send urine samples for qualitative testing under HCPCS code G0431, which carried a reimbursement rate of $100, rather than the $19.84 that would have been applicable if the testing

had been done on-site.

CPS developed, and Kroll approved, Urine Drug Screening Guidelines in March 2014, which were distributed to CPS providers. Under these Guidelines, all new patients were to be tested, and established patients receiving narcotics would be tested at least six times per year, more if the circumstances warranted. (Doc. No. 65 ¶¶ 126–27.) Following issuance of this guideline, CPS had weekly conference calls with providers to ensure that they were ordering and billing for the full panel of UDT, including specimen validity testing. (*Id.* ¶ 129.)

In October 2014, at Davis's direction and with Kroll's approval, CPS emailed providers notifying them that they would be required to sign a form for a standing order on UDT that would be done at CPS's off-site lab in Franklin, Tennessee. (*Id.* ¶ 132.) Kroll and Dickerson executed the standing order. (*Id.* ¶ 134.)

The training manual for CPS's electronic medical record system, eClinical Works, which was made available to CPS providers in or about April 2015, contained a template for ordering UDT, which required providers to order both qualitative and quantitative drug screens. CPS also required providers to order UDT for established patients every two months, regardless of whether there was an individualized need for testing that frequently. (Doc. No. 65 ¶ 135.) Notably, according to the Consolidated Complaint, CPS required providers to order quantitative testing from the outset, before they obtained results from the qualitative testing. If the drug screen was negative, there was no medical necessity for quantitative testing. (*Id.* ¶ 137.)

Even though the results from the UDT would often not be available for seven to ten days, CPS providers would frequently prescribe pain medication, including opioids, without having the results and, moreover, would frequently not review or consider the results, when they became available, in making prescribing decisions. Thus, for example, providers would continue to

prescribe opioid pain medication for patients who tested negative for opioids, which should have given rise to questions about whether the patients were giving away or selling their pain medication. (*Id.* ¶¶ 138–39.) In addition, pursuant to CPS policies approved by Kroll, even where POC testing was considered medically necessary, CPS locations lacked the equipment necessary to perform it. (*Id.* ¶ 140.)

The Consolidated Complaint alleges, in sum, that CPS should not have utilized a standing order for UDT, because it did not allow for an individualized determination of patient-specific risk and medical necessity, did not comply with the requirements of "various MACs," and resulted in medically unnecessary and duplicative testing. (*Id.* ¶¶ 144–47.)

In July 2014, based on the sheer number of UDTs ordered by CPS, CMS, through AdvanceMed, a Zone Program Integrity Contractor ("ZPIC"), began performing an audit covering claims from January 1, 2012 through May 31, 2014. Thus, when CPS issued its formal standing order in October 2014, it was already on CMS's radar screen for overutilization of UDT. While its policies were under scrutiny, CPS's Compliance Department issued revised Urine Drug Screening Guidelines, effective September 1, 2015, which Kroll approved. These Guidelines noted that it was not appropriate to order UDT on every patient at every visit and that a risk assessment was required to establish medical necessity. A revised policy issued in March 2016, approved by Kroll, purported to provide risk stratification but still required even low risk patients to receive a full set of UDT at least once per year. (Doc. No. 65 ¶ 166.) Moreover, despite these policies and additional training provided to CPS's providers, there was little reduction in the number of UDTs ordered, particularly by providers in certain East Tennessee clinics, as a result of which CPS determined that each provider should receive individual training with Kroll personally.

One of the providers, Nurse Practitioner Anita Bayles, failed to change her practices of

over-ordering UDT; she was also noted to be seeing more patients than was appropriate and over-prescribing opioids. The Compliance Committee, including Kroll, voted unanimously to terminate Bayles in September 2016. At a telephone conference call involving members of the compliance committee, Davis, and Bayles' supervising physician, Davis made the decision to keep Bayles on staff because of her ability to generate revenue. Kroll was aware of this decision but failed to take any action. (*Id.* ¶¶ 171–74.)

Regardless, because of excessive billing, Cahaba notified CPS that seven specific East Tennessee providers would be placed on "prepayment review," meaning that any claims submitted by these providers would not be processed until documentation confirmed that the services were medically necessary and properly reimbursable. (*Id.* ¶ 178.)

CPS issued another set of UDT guidelines in November 2016, approved by Kroll. These guidelines did not mention risk stratification and recommended testing at least six times per year for patients receiving narcotics, and more if there were "red flags." (*Id.* ¶ 179.) Moreover, despite the issues raised by the audit, as of February 2017, "Kroll was still in favor of standing orders that did not emphasize individual patient risk." (Doc. No. 65 ¶ 180.)

The March 2017 update to CPS's UDT Guidelines included a suggested table of testing frequency based on low, moderate, and high risk groups. The guidelines indicated that new patients being considered for opioid therapy should be tested and that testing should be based on documented medical necessity and reviewed by the provider for the risk group determination. (Doc. No. 65 ¶ 181.)

In April 2017, CPS's Director of Provider Education notified CPS providers that, effective May 1, 2017, they would have the option of choosing a complete panel or a limited one, which did not test for illegal substance, and would continue to have the option of ordering additional testing

"a la carte," providing there was medical necessity. (*Id.* ¶ 182.)

Beginning on February 26, 2018, Palmetto Government Benefit Administrator, LLC ("Palmetto") became the MAC for Tennessee. Palmetto had more stringent requirements for approval of UDT than Cahaba had. (*Id.* ¶ 183.) In preparation for the change of administrators, CPS notified its providers that drug screen orders had to be placed "AFTER the patient has been seen by the provider"—thus requiring individualized assessment. Finally, as of March 2018, it was clear that "CPS providers could no longer use a 'panel' to order UDS." (*Id.* ¶¶ 184–85.) The Consolidated Complaint alleges, "[u]pon information and belief, [that] virtually all CPS locations continued the practice of using a standing order that incorporated bundles of drug tests, including specimen validity testing and automatic quantitative testing without regard to patient risk factors from 2014 until Palmetto became the MAC for Tennessee on February 26, 2018." (*Id.* ¶ 187.)

The Consolidated Complaint alleges that CPS billed the Government Health Care Programs for millions of dollars for the reimbursement of largely unnecessary medical testing, including over $2,000,000 for UDT claims submitted by Kroll as the rendering provider. (*Id.* ¶¶ 190, 196.)

Specimen Validity Testing

The Consolidated Complaint also alleges that specimen validity testing is *per se* not covered and that CPS routinely billed the Government Health Care Programs for specimen validity testing using certain codes, including CPT codes 82565, 82560, 82670, 83986, 84075, and 94295, which are not reimbursable by Government Health Care Programs and lack medical necessity. If the Government Health Care Programs had known that the specimen validity testing lacked the requisite medical documentation, was not medically necessary, and otherwise did not satisfy the criteria for reimbursement, they would not have paid CPS for these claims. From 2011 through

2018, Medicare paid CPS over $1,000,000 for 124,070 claims and 209,395 'claim lines" for specimen validity testing under CPT codes 82565, 82570, 82670, 83986, 84075 and 84295. Of that amount, $82,865.24 is attributable to Kroll. (Doc. No. 65 ¶¶ 199–205.)

The Consolidated Complaint includes specific examples of improperly submitted claims for reimbursement of specimen validity testing, including allegations relating specifically to Kroll:

> k. Kroll submitted a claim to Medicare for specimen validity testing on November 16, 2011 on patient D.M. under CPT codes 82570 (creatinine) and 83986 (pH), for which Medicare paid CPS a total of $10.14.
>
> l. Kroll submitted a claim to Medicare for specimen validity testing on January 24, 2018 on patient R.S. (a male) under CPT code 82670 (estradiol-hormone), for which Medicare paid CPS a total of $33.80. The address for patient R.S. is listed in North Carolina.
>
> m. Kroll submitted a claim to Medicare for specimen validity testing on April 3, 2018 on patient P.B. under CPT codes 82565 (creatinine) and 84075 (phosphatase), for which Medicare paid CPS a total of $12.46.

(*Id.* ¶ 206(k)–(m).)

The Consolidated Complaint alleges that CPS's "overall UDS policies" resulted in the submission of claims for duplicative drug tests that were medically unnecessary and for quantitative drug tests that were not medically necessary and were performed even when the qualitative drug test were negative. As an example of Kroll's billing for this type of event, the government submits that

> Kroll submitted a claim to Medicare on November 16, 2011 on patient D.M. under CPT codes 81003 (automated urinalysis), 84311 (chemical analysis using spectrophotometry), and G0431 (qualitative testing), for which Medicare paid CPS a total of $115.32. CPS also was paid for specimen validity testing that Kroll submitted on this patient.

(*Id.* ¶ 208(b).)

Other Medically Unnecessary Testing

In addition to UDS, CPS began performing pharmacogenetic blood testing on patients in

May 2013, which purportedly screened for variations in genes to determine how quickly a patient might metabolize certain drugs. (Doc. No. 65 ¶ 213.) The government alleges that the defendants knew or should have known that the genetic testing that CPS and its providers were performing was not reimbursable by the Government Health Care Programs. The government alleges that each of the CPT codes CPS used to bill for genetic blood tests had specific limitations and requirements for medical necessity. For example, one of the codes CPS used to bill for genetic blood tests was 81225. Pursuant to an LCD issued by Cahaba effective October 1, 2015, for genetic testing under CPT code 81225 to be medically necessary, the patient had to have acute coronary syndrome ("ACS") and have been undergoing percutaneous interventions with Plavix therapy. (*Id.* ¶ 216 (citing Cahaba LCD L35660).) The Consolidated Complaint alleges that, in nearly every case in which genetic blood testing was performed, CPS lacked medical necessity. (*Id.* ¶ 221.) In addition, CPS did not maintain the required supporting documentation or use the results of the genetic tests in providing treatment for its patients. (*Id.* ¶ 222.)

Beginning at least as of November 2013, CPS provided a $25 bonus to mid-level providers as an incentive to order genetic testing to be performed at CPS's testing facility. (*Id.* ¶ 223.) This incentive worked. An internal audit in August 2015 found excessive genetic testing without documentation of medical necessity. The ZPIC audit expressly flagged excessive genetic testing as a problem, specifically finding insufficient documentation and no medical necessity for CPS to conduct genetic testing on the patients it sampled. (*Id.* ¶ 227–28.)

CPS and Kroll specifically were aware of excessive genetic testing in the East Tennessee clinics, with many providers ordering genetic testing on all new patients. Despite training conducted in late 2015, this over-testing continued. Kroll was aware of this fact, but CPS continued to bill the Government Health Care Programs for unnecessary genetic testing from 2013 until it

ceased operations in 2018. (*Id.* ¶¶ 233–34.) From 2013 to 2018, the United States paid CPS approximately $2 million for 3,805 claims submitted to Medicare with 11,738 claim lines for genetic testing under CPT codes 81225, 81226, 81227, 81355 and 81401. Of this amount, $131,054.74 is attributable to Kroll for 454 claims and 1,852 claim lines. (*Id.* ¶ 239.)

Beginning in 2012, CPS also began performing psychological testing on patients, purportedly to determine whether they were at risk for addiction, depression, and suicide. It performed such psychological testing by having patients answer questions on an iPad. (*Id.* ¶ 241.) The plaintiffs allege that this type of testing was not reimbursable by the Government Health Care Programs and that the defendants knew or should have known that it was not reimbursable. The Government Health Care Programs only reimburse for certain types of psychological testing if it is medically necessary, under CPT code 91603, and reimbursement rates ranged from $19.88 to $50.43 per test during the relevant time frame. (*Id.* ¶¶ 242–43.)

In support of its assertion that the defendants knew or should have known that the testing was not medically necessary, the government claims that "[s]ome CPS providers felt that there was no medical necessity for the iPad tests" and that CPS never developed any plan or formal policy for responding to the results of iPad testing—for instance, if they showed that a patient had suicidal ideation. In addition, CPS was aware that private insurers did not reimburse for psychological testing performed on an iPad by a provider who was not treating mental health issues, because it was not deemed medically necessary. (*Id.* ¶ 244.)

Nonetheless, CPS offered mid-level providers a $5.00 bonus for every iPad test they ordered (Doc. No. 65 ¶ 246), and it negotiated a flat rate with its vendor so that all patients could be tested, regardless of whether the test was covered, without additional cost to CPS (*Id.* ¶ 248). CPS's managerial staff put pressure on providers to order the testing. (*Id.* ¶¶ 250–52.) And, to

substantiate the testing where medical necessity was lacking, CPS's billing department would review progress notes and adjust diagnoses. As an example, the plaintiffs allege that CPS would characterize a claim of trouble sleeping as insomnia that could lead to depression. (*Id.* ¶ 247.) In some instances, the tests were billed under Kroll's provider number, even when he was not the rendering physician. (*Id.* ¶ 253.)

From 2012 to 2018 when it ceased operating, CPS submitted 145,767 claims for iPad testing under CPT code 96103, for which Medicare alone paid over $2.4 million. Of that amount, $34,656.28 was attributable to Kroll. The plaintiffs provide examples of claims submitted by various providers that it believes were improperly submitted.

The Consolidated Complaint also alleges that Kroll and the other Owners were aware of the fraudulent conduct at issue; that they personally submitted false claims for non-reimbursable specimen validity, genetic and iPad testing and for medically unnecessary UDT; that they were aware of the ZPIC audit; that they turned a blind eye to the medically unnecessary UDT by others, because they reaped the financial benefits of the standing order; that they failed to take any steps to stop Davis from engaging in unlawful conduct and continued to reward him financially; and that Kroll personally, as Chief Medical Officer, had knowledge of the daily activities of CPS providers and was directly involved in addressing the problems identified through the ZPIC audit. (*Id.* ¶¶ 364–78.)

In relevant part, the Consolidated Complaint asserts claims against Kroll based on (1) alleged violations of 31 U.S.C. § 3729(a)(1)(A) and Tenn. Code Ann. § 71-5-182(a)(1)(A) by presenting false claims for tests that are not reimbursable by the Government Health Care Programs, were not medically necessary, or both (Doc. No. 65 ¶¶ 434–38, Count I); (2) alleged violations of 31 U.S.C. § 3729(a)(1)(B) and Tenn. Code Ann. § 71-5-182(a)(1)(B) for making or

using, or causing to made or used, false records or statements related to testing, including false certifications and representations on Forms 1500 and their electronic equivalent to obtain approval for, and payment of, false or fraudulent claims by the government (Doc. No. 65 ¶¶ 439–44, Count II); (3) alleged violations of 31 U.S.C. § 3729(a)(1)(G) and Tenn. Code Ann. § 71-5-182(a)(1)(D), for making, using, or causing to made or used, false records or statements material to obligations to pay or transmit money to the government or for concealing, improperly avoiding, or decreasing obligations to pay or transmit money to the government (Doc. No. 65 ¶¶ 445–48); and (4) alleged violations of 31 U.S.C. § 3729(a)(1)(G)[3] and Tenn. Code Ann. § 71-5-182(a)(1)(D), for failing to return overpayments to CPS for false claims of which Kroll was aware (Doc. No. 65 ¶¶ 449–52 (Count IV)).[4]

Kroll seeks the dismissal of Counts I through III "as they pertain to the government's allegations of fraudulent schemes involving UDT, genetic testing under CPT code 81225, and psychological testing," and dismissal of Counts 1 through IV "to the extent they seek to impose vicarious liability on Dr. Kroll for allegedly fraudulent claims submitted by other CPS employees." (Doc. No. 100, at 3 n.2.)[5]

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[3] The government actually references 31 U.S.C. § 3729(a)(7) in both the Consolidated Complaint and its Response to the Motion to Dismiss. (Doc. No. 65 ¶ 450; Doc. No. 113, at 10.) However, in 2009, Congress passed the Fraud Enforcement and Recovery Act, Pub. L. No. 111-21, 123 Stat. 1617 (2009), which renumbered that provision as § 3729(a)(1)(G). *See Chesbrough v. VPA, P.C.*, 655 F.3d 461, 466 n.2 (6th Cir. 2011).

[4] As referenced above, the Consolidated Complaint also states claims against Kroll and the other defendants for violation of the Federal Priority Statute, 31 U.S.C. § 3713 *et seq.* (Count V); payment by mistake (Count VI); unjust enrichment (Count VII); and common law fraud (Count VIII). Kroll's Motion to Dismiss does not address these claims.

[5] The motion does not seek dismissal of these Counts insofar as they pertain to the submission of allegedly false claims related to other types of medical services, specifically including acupuncture.

III. STANDARD OF REVIEW

Two standards of review govern the consideration of a motion to dismiss claims under the False Claims Act. First, under Rule 12(b)(6), "all well-pleaded material allegations of the pleadings" are accepted as true, and those allegations must "be sufficient to give notice to the defendant as to what claims are alleged, and . . . plead 'sufficient factual matter' to render the legal claim plausible, *i.e.*, more than merely possible." *Fritz v. Charter Twp. of Comstock*, 592 F.3d 718, 722 (6th Cir. 2010) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 677 (2009)). That is, under the general pleading standards of Rule 8, the factual allegations in the complaint need not be detailed, although "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of a cause of action's elements will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

Second, "[t]he heightened pleading standard set forth in Rule 9(b) applies to complaints brought under the FCA." *Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559, 563 (6th Cir. 2003). Under that rule, "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity," while "[m]alice, intent, knowledge, and other condition of mind of a person may be averred generally." Fed. R. Civ. P. 9(b). To comply with Rule 9(b), "a plaintiff, at a minimum, must 'allege the time, place, and content of the alleged misrepresentation on which he or she relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud.'" *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 504 (6th Cir. 2007) (quoting *Coffey v. Foamex L.P.*, 2 F.3d 157, 161–62 (6th Cir. 1993)).

As indicated above, the FCA "imposes civil liability on any person who knowingly submits false claims to the government." *United States ex rel. Digital Healthcare, Inc. v. Affiliated Comput. Servs., Inc.*, 778 F.Supp.2d 37, 44–45 (D.D.C. 2011) (citing 31 U.S.C. §§ 3729–3733). Section 3729(a)(1)(A) creates liability for "any person who . . . knowingly presents, or causes to be

presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). To state a "presentment" claim under the FCA, the government must sufficiently plead that (1) the defendant presented, or caused to be presented, a claim for payment or approval; (2) the claim was false or fraudulent; and (3) the defendant's acts were undertaken "knowingly," meaning with actual knowledge of the information, or with deliberate ignorance or reckless disregard for the truth or falsity of the claim. *United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 838 F.3d 750, 761 (6th Cir. 2016).

Subsection (a)(1)(B) imposes liability on any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B). To state a claim under this provision, the plaintiff must sufficiently plead

> [1] that the defendant [made] a false statement or create[d] a false record [2] with actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the information; [3] that the defendant . . . submitted a claim for payment to the federal government; . . . and [4] that the false statement or record [was] material to the Government's decision to make the payment sought in the defendant's claim.

U.S. ex rel. Sheldon v. Kettering Health Network, 816 F.3d 399, 408 (6th Cir. 2016) (quoting *U.S. ex rel. SNAPP, Inc. v. Ford Motor Co.*, 618 F.3d 505, 509 (6th Cir. 2010)).

To state a claim under § 3729(a)(1)(G), often referred to as the "reverse-false-claim" provision of the FCA, the plaintiff must allege facts showing that the defendants received overpayments from the government and failed to refund those payments. *U.S. ex rel. Harper v. Muskingum Watershed Conservancy Dist.*, 842 F.3d 430, 433 (6th Cir. 2016) "Alternatively, a section 3729(a)(1)(G) violation is made out if the relator pleads adequate proof that the defendant made a false record or statement at a time that the defendant owed to the government an obligation—a duty to pay money or property." *U.S. ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905, 916 (6th Cir. 2017) (citations and internal quotation marks denied), *cert. denied*,

138 S. Ct. 2582 (2018).

The elements of a claim under the TMFCA are "virtually identical" to those of an FCA claim. *United States v. UT Med. Grp., Inc.*, No. 2:12-CV-02139-JPM-TMP, 2014 WL 12611244, at *4 n.2 (W.D. Tenn. May 21, 2014) (comparing 31 U.S.C. § 3729(a)(1)(A) ("[A]ny person who[] knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval . . . is liable to the United States Government for a civil penalty[.]) *with* Tenn. Code Ann. § 71-5-182(a)(1)(A) ("[A]ny person who[] [k]nowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval under the medicaid program . . . is liable to the state for a civil penalty[.]"). "Accordingly, the analysis of the sufficiency of the pleading is equally applicable to both statutory claims." *Id.*; *accord U.S. ex rel. Nudelman v. Int'l Rehab. Assocs., Inc.*, No. CIV.A. 00-1837, 2006 WL 925035, at *12 (E.D. Pa. Apr. 4, 2006) (applying the same analysis to FCA and TMFCA claims, noting that the state statute "read[s] similarly and [is] substantively the same as the FCA").

IV. DISCUSSION

A. The Government's Theories of Liability

The government's FCA claims are premised upon its assertion that Kroll and other CPS medical providers submitted thousands of claims for services that were not actually provided, that they knew or should have known were expressly not covered by the Government Health Care Programs, or that were medically unnecessary. Specifically, the government characterizes its claims as based upon:

> (i) fraud in not providing the services represented (*i.e.*, certain testing represented was not the testing performed); (ii) an express false certification that the testing performed was reasonable and medically necessary; and (iii) an implied false certification that the testing complied with the conditions set forth in the Cahaba and Palmetto LCDs, which were mandatory for CPS, and material to payment determinations of the Government Health Care Programs.

(Doc. No. 113, at 19.)

Kroll does not actually contend that the allegations of fraud are not pleaded with sufficient particularity, and he does not appear to contest claims based upon fraud for seeking payment for services that were not actually provided. Instead, he argues that: (1) the express false certification claims premised upon false certifications of medical necessity fail to state a claim for which relief may be granted, because opinions about medical necessity cannot be objectively false; (2) the government's implied false certification claims fail, because the LCDs issued by various MACs are non-binding interpretive guidance, and the FCA claims premised upon "[a]llegations of false certification of compliance with such guidance therefore cannot state a claim under the FCA" (Doc. No. 100, at 3); and (3) the Consolidated Complaint fails to state a claim against Kroll based upon his vicarious liability for the false claims submitted by other CPS employees, because the FCA incorporates a strict scienter requirement.

A. Express False Certification Claims – Medical Necessity

An entity seeking reimbursement for services provided to Medicare patients must submit a CMS Form 1500 to the Medicare contractor. *See United States ex rel. Hobbs v. MedQuest Assocs.*, 711 F.3d 707, 711 (6th Cir. 2013). "These forms reflect the treatment or services provided and identify the provider or supplier who provided them. Tests, supplies, and services are correlated to a series of unique numbers, called CPT codes, which quickly convey to the [MAC] what reimbursable expenses the provider has incurred." *Id.* The CMS Form 1500 form requires the provider to "certify that the services listed above were medically indicated and necessary to the health of this patient and were personally furnished by [the provider] or [his] employee under [his] personal direction." *Id.*

As distinct from "obvious cases of fraud, such as where a provider bills for procedures or services that were not rendered or not necessary," *U.S. ex rel. Antoon v. Cleveland Clinic Found.*,

978 F. Supp. 2d 880, 889 (S.D. Ohio 2013), express false certification claims allege that the defendant "signed or otherwise certified to compliance with some law or regulation on the face of the claim submitted." *U.S. ex rel. Hobbs v. MedQuest Assocs.*, 711 F.3d 707, 714 (6th Cir. 2013). The government's express false certification theory is based upon allegations that Kroll falsely certified on CMS Forms 1500 that claims he submitted were medically necessary when he knew, as that term is defined by the statute, that they were not.

Kroll argues that, insofar as the plaintiffs' claims are premised upon a "bare assertion" that the testing at issue—UDT, genetic testing under CPT code 81225, and iPad psychological testing—was not medically "reasonable and necessary," such claims fail as a matter of law. (Doc. No. 100, at 13.) He argues that, in order for a claim to be false under the FCA, it must be "objectively false" and that, in the absence of a controlling rule establishing when the relevant testing is permissible, the government's theory of recovery "regarding Dr. Kroll's conduct as a medical provider amounts to inappropriate—and legally insufficient—second guessing of the medical judgment exercised by Dr. Kroll." (Doc. No. 100, at 13–14.) Second, he insists that, in the absence of some "controlling guidance situating that phrase to a particular medical context, FCA liability cannot follow." (*Id.* at 16.)

Regarding his first argument—that the government's express false certification claim fails because Kroll's professional opinion as to medical necessity cannot be shown to be objectively false for purposes of stating a claim under the FCA—those courts presented with this argument have largely rejected it, particularly in the context of ruling on a motion to dismiss. *See, e.g.*, *United States v. Adams*, 371 F. Supp. 3d 1195, 1211 (N.D. Ga. 2019) ("For purposes of this Order, the Court agrees with those courts that have concluded that a physician's subjective medical opinions or judgments can be false for purposes of the FCA. Defendants therefore are not entitled to

dismissal based on this argument. Further, most of the cases that Defendants cite involve decisions on summary judgment."); *see also United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 742 (10th Cir. 2018) ("It is possible for a medical judgment to be 'false or fraudulent' as proscribed by the FCA."); *United States v. Paulus*, 894 F.3d 267, 275 (6th Cir. 2018) ("[O]pinions are not, and have never been, completely insulated from scrutiny. At the very least, opinions may trigger liability for fraud when they are not honestly held by their maker, or when the speaker knows of facts that are fundamentally incompatible with his opinion."); *U.S. ex rel. Groat v. Boston Heart Diagnostics Corp.*, 255 F. Supp. 3d 13, 28 (D.D.C. 2017) ("[T]he Court cannot determine that the relator's allegations regarding medical necessity necessarily involve a difference of clinical judgment because to do so would require the Court to weigh the evidence, which is inappropriate at this stage of the litigation."), *amended on reconsideration in part*, 296 F. Supp. 3d 155 (D.D.C. 2017).

The Sixth Circuit has recognized that FCA liability may be based on express false certifications that medical testing was reasonable and medically necessary. *MedQuest Assocs.*, 711 F.3d at 715 (finding that the only "express certification" on the defendant's CMS Form 1500 was "that the services listed on the form were 'medically indicated and necessary for the health of the patient'" but that the medical necessity of the tests at issue there had never been contested). And the Tenth Circuit has expressly held "that a doctor's certification to the government that a procedure is 'reasonable' and 'necessary' is 'false' under the FCA if the procedure was not reasonable and necessary under the government's definition of the phrase." *Polukoff*, 895 F.3d at 743.

In this case, the government adequately alleges that there was no medical need or basis for submitting claims for secondary drug testing—that is, quantitative testing—on every patient tested,

including those who tested negative for any drug, or for duplicative testing.[6] (*See* Doc. No. 65 ¶¶ 126–39, 144–50, 162, 171.) Regarding the specimen validity testing, the Consolidated Complaint alleges that, under express Medicare guidance and "other regulations," this testing is not reimbursed when conducted in connection with UDS and when it lacks medical necessity—that is, when it is not done for a purpose related to diagnosis or treatment. (*Id.* ¶¶ 118, 199, 202–03.) The plaintiffs also allege that CPS was conducting genetic testing on patients without medical necessity, including performing genetic testing more than once on at least three patients, and that the Government Health Care Programs considered genetic testing to be investigatory or covered only in limited circumstances that did not apply to CPS patients. (*Id.* ¶¶ 214–19, 221, 227–31, 234–35.) Finally, the Consolidated Complaint alleges that CPS lacked any medical necessity for the iPad psychological testing that it was pushing its providers to conduct, even though they did not utilize the results in treating patients and, indeed, had no protocol in place for responding to it, and CPS was aware that the Government Health Care Programs only reimburse for psychological testing that is medically necessary. (*Id.* ¶¶ 241–45, 255.) The court finds that these allegations are sufficient to establish that CPS and Kroll personally submitted legally false claims—claims they knew were for medically unnecessary services—despite certifying that the claims were medically necessary.

Moreover, contrary to the defendant's assertions that the plaintiffs' claims are not based upon an express statutory or regulatory provision, as set forth above, Medicare coverage generally

[6] Kroll also attempts to argue, as a factual matter, that UDT was not medically unnecessary, because the Tennessee Chronic Pain Guidelines provide that "confirmation [quantitative] testing is required prior to outset of [chronic opioid therapy]." (Doc. No. 116, at 5 n.5.) The court at this juncture must presume that the plaintiff's factual allegations are true, however, and the plaintiffs allege as a factual matter that ordering quantitative testing of a substance prior to confirmation that such substance is, in fact, in the patient's blood stream is *per se* medically unnecessary.

"is limited to services that are medically 'reasonable and necessary.'" *United States v. Popov*, 742 F.3d 911, 912–13 (9th Cir. 2014) (citation omitted); *see Detroit Receiving Hosp. & Univ. Health Ctr. v. Sebelius*, 575 F.3d 609, 611 (6th Cir. 2009) ("Under both Part A and Part B, Medicare pays for services that are medically reasonable and necessary for the beneficiary."); *Hays v. Sebelius*, 589 F.3d 1279, 1283 (D.C. Cir. 2009) ("[I]tems or services . . . must be reasonable and necessary to qualify for Medicare coverage."); 42 U.S.C. § 1395y(a)(1)(A) (proscribing payment under Medicare Part A or Part B unless items or services are "reasonable and necessary"); 42 C.F.R. 411.15k (disallowing payment for certain types of services, tests, and examinations that are not "reasonable and necessary"). Thus, as the Sixth Circuit has recognized, medically unnecessary "nondiagnostic" tests billed to the government can "form the basis of an FCA claim." *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 468 (6th Cir. 2011). As the court explained there:

> A test known to be of no medical value . . . that is billed to the government would constitute a claim for worthless services, because the test is so deficient that for all practical purposes it is the equivalent of no performance at all. If [the defendant] sought reimbursement for services that it knew were not just of poor quality but had no medical value, then it would have effectively submitted claims for services that were not actually provided. This would amount to a "false or fraudulent" claim within the meaning of the FCA.

Id. at 468 (internal quotation marks and citations omitted).

The Consolidated Complaint specifically alleges that Kroll personally provided medically unnecessary services. For each type of fraud alleged, the Consolidated Complaint sets forth specific examples of claims that Kroll submitted, in violation of Medicare statutes and regulations, for which CPS was paid. (*See, e.g.*, Doc. No. 65 ¶¶ 206, 208, 240, 258.) And, according to the plaintiffs, each claim Kroll submitted would have been accompanied by a CPS Form 1500 through which he falsely certified that the services provided were reasonable and medically necessary.

At the pleading stage, this is all that is required. As set forth above, Kroll does not allege

that falseness is not adequately alleged. Instead, he asserts only that he is not liable as a matter of law, because the Consolidated Complaint does not adequately allege that he violated binding Medicare statutes and regulations and that FCA liability cannot be premised on medical judgment. He is incorrect on both counts, and the court finds that he is not entitled to dismissal of any of the claims in the Consolidated Complaint on this basis.

B. Claims Based on Violation of Local Coverage Determinations

By statute, LCDs announce prospectively "whether or not a particular item or service is covered" by that contractor. 42 U.S.C. § 1395ff(f)(2)(B). The role of an LCD is essentially to interpret what Medicare would consider medically necessary and what documentation is needed to support reimbursement. Generally, "LCDs are mandatory for areas they cover." *U.S. ex rel. Ryan v. Lederman*, No. 04-CV-2483, 2014 WL 1910096, at *5 (E.D.N.Y. May 13, 2014); *see also United States v. Adams*, 371 F. Supp. 3d 1195, 1213 (N.D. Ga. 2019) (noting that, even though LCDs are not binding on the courts, courts give them "substantial deference where they apply"); *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1012 (D. Nev. 2006) ("[LCDs] set regional coverage determinations that govern in the absence of or as an adjunct to a national policy." (citing 68 Fed. Reg. 63,692, 63,693 (Nov. 7, 2003)). Several courts have held that noncompliance with LCDs may give rise to FCA liability. *See, e.g.*, *Adams*, 371 F. Supp. 3d at 1213; *U.S. ex rel. Youn v. Sklar*, 273 F. Supp. 3d 889, 896 (N.D. Ill. 2017); *United States v. Space Coast Med. Assocs.*, LLP, 94 F. Supp. 3d 1250 (M.D. Fla, 2015); *Ryan*, 2014 WL 1910096 at *6.[7]

[7] Kroll points to one opinion from this district that appears to doubt whether violation of an LCD could give rise to a claim under the FCA. In *United States ex rel. McMullen v. Ascension Health*, No. 3-12-0501, 2013 WL 6073549, at *2 (M.D. Tenn. Nov. 18, 2013) (Campbell, J.), the court granted the defendant's motion to dismiss the FCA claims against him for failure to "identif[y] in the Amended Complaint a single specific claim which was submitted to Medicare for payment" or a "single specific claim in which Defendants made a false statement." *Id.* at *2. The plaintiff's claims were premised upon violation of LCDs. The court noted that "[w]hether the LCDs applied to Defendants is a contested factual issue, but Relator does not cite to a statute or

Kroll's motion to dismiss the claims against him to the extent they rely on the LCDs is premised primarily upon his reading of *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019). In *Allina*, the Supreme Court was called upon to interpret 42 U.S.C. § 1395hh(a)(2), which states:

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

The Court held that this statute means that an agency change in the interpretation of a rule governing payment to hospitals had to go through notice and comment to be implemented. *Allina*, 139 S. Ct. at 1813–15. *Allina* involved a new Medicare payment formula posted by CMS on its website that had the effect of substantially reducing payments to hospitals that served low-income patients. *Allina*, 139 S. Ct. at 1808. The Supreme Court invalidated the rule, holding that it was a "substantive legal standard" that could not go into effect without the notice and comment period required by § 1395hh(a)(2). *Allina*, 139 S. Ct. at 1811–14, 1817. In reaching that conclusion, the Court distinguished between the term "substantive legal standard" under the Medicare Act and the term "substantive rule" under the Administrative Procedures Act ("APA") and explicitly left open the possibility that interpretive rules—defined as rules that "merely clarify or explain existing law or regulations," *Powderly v. Schweiker*, 704 F.2d 1092, 1098 (9th Cir. 1983), and which are excluded from the definition of "substantive rules" under the APA—could nonetheless qualify as substantive legal standards under § 1395hh(a)(2) and thus trigger a requirement for notice and comment under the Medicare Act. *Id.* at 1814; *see also Select Specialty Hosp.-Denver, Inc. v. Azar*,

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regulation that conditions payment of a Medicare claim on compliance with any LCD." *Id.* at *2 n.4. The court there was not squarely presented with, and did not answer, the question of whether violation of an LCD could ever give rise to FCA liability.

391 F. Supp. 3d 53, 67 (D.D.C. 2019) ("As a result [of *Allina*], in some circumstances CMS [will] not be obligated to conduct notice-and-comment rulemaking under the APA but is nonetheless required to do so under the Medicare Act.").

At least one district court, applying *Allina*, has held that an LCD may establish a substantive legal standard and, if so, must go through the notice and comment period prescribed by § 1395hh(a)(2). *Agendia, Inc. v. Azar*, No. SA CV 19-0074-DOC (JDEx), 2019 WL 7166974, at *9 (C.D. Cal. Oct. 29, 2019). The court in *Agendia* held that the LCD at issue in that case, which basically established "non-coverage" for all molecular diagnostic tests of the type supplied by the plaintiff that were not explicitly covered by an NCD, a LCD, or other express policy, was merely interpretive for purposes of the APA, *id.* at *7 (citing *Erringer v. Thompson*, 371 F.3d 625, 631 & n.10 (9th Cir. 2004)), but was a substantive legal standard under the Medicare Act that had been unlawfully promulgated without notice and comment, *id.* at *9–10.

Kroll relies on *Allina* to support the proposition that an FCA claim cannot be premised upon non-compliance with an LCD, because LCDs are not promulgated in accordance with notice and comment procedures. However, *Allina* did not concern LCDs and certainly did not establish that *all* LCDs set forth substantive legal standards, nor did it address the question of whether a false certification of compliance with an LCD may form the basis of a claim under the FCA. Moreover, neither party here has actually briefed the question of whether the particular LCDs at issue should be considered to establish substantive legal standards, nor have the parties addressed the question of whether *Allina* has any application at all in the context of a case asserting FCA claims, as opposed to a case specifically contesting the denial of Medicare claims for reimbursement. At this juncture, the court does not read *Allina* to support dismissal of any claims asserted in this case.

Kroll also argues that the Consolidated Complaint improperly attempts to impose liability on him and other defendants based on purported violations of LCDs that occurred before the LCDs actually went into effect or based on purported violations of LCDs issued in other regions by other MACs. The court does not construe the Consolidated Complaint in this way. Rather, the reference to other MACs and other LCDs appears to be intended to bolster the allegations that much of the testing Kroll and other CPS providers were ordering was not medically necessary, regardless of whether a binding LCD reached the issue at the time.

Kroll also argues that he cannot be liable under the FCA based on any failure to comply with an LCD, because the Consolidated Complaint details his "multiple, successive efforts to ensure that UDT policies and practices were compliant" and that CPS's practices changed to become compliant with the LCDs regarding urine drug testing once the applicable LCDs were implemented. (Doc. No. 100, at 21 (citing Doc. No. 65 ¶¶ 158, 161, 163–66, 170, 181); *see id.* at 18–19.) In his Reply, Kroll asserts that the government is "apparently unable to refute [his] argument that CPS's UDT policies and practices were compliant with the LCDs once the LCDs did come into effect" and, instead, pretends "as if Dr. Kroll never made that argument." (Doc. No. 116, at 2.) Notwithstanding, the Consolidated Complaint does not allege that CPS's UDT practices were ever compliant with Cahaba's LCDs. Instead, it asserts that, irrespective of whatever policies were nominally in place, CPS's practices did not actually change substantially until 2018, when Palmetto became the MAC and instituted stricter oversight. (Doc. No. 65 ¶¶ 183–87.) Kroll's assertion that CPS's practices changed under Cahaba's LCDs constitutes an attempt to refute a factual allegation in the pleading, which is inappropriate in the context of a motion to dismiss.

In sum, this court agrees with those courts that have found that violation of an LCD may give rise to an FCA claim and further concludes, on the sparse record and minimal argument

offered thus far, that *Allina* did not foreclose that possibility. The Consolidated Complaint adequately alleges facts to support claims based on alleged violations of Cahaba's LCDs.

C. Vicarious Liability

Finally, Kroll argues that, to the extent the government is trying to hold him vicariously liable for "***all*** allegedly false claims submitted by CPS personnel throughout Dr. Kroll's tenure based on Dr. Kroll's ownership interest and leadership positions," that effort fails because the FCA does not permit "this sweeping extension into vicarious liability." (Doc. No. 100, at 19.) Rather, he insists, the FCA contains a "'rigorous' scienter requirement" that does not permit liability merely on the basis of negligent oversight. (*Id.* at 19–20.)

In response, the government insists that it is not seeking to hold Kroll *vicariously* liable. Rather, it seeks to impose liability based upon allegations that Kroll "*personally* set the policies for CPS, was aware of the internal conduct, was aware of wrongdoing [by] other providers, including [through] the overutilization of urine drug, genetic, and psychological testing, which continued even after training," and that Kroll both "allowed the false claims to be submitted and never sought to reimburse the United States or Tennessee for any overpayment of which he was aware." (Doc. No. 113, at 28 (citing Doc. No. 65 ¶¶ 27, 86, 88, 127, 132, 140, 158, 161, 163, 169–74, 230–33, 335, 404, 410).)

As Kroll argues, the FCA indeed incorporates a "rigorous" scienter requirement. *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 2002 (2016). Nonetheless, the statute does not require "proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1)(B). Rather, the FCA defines "knowing" to

> mean that a person, with respect to information–
> (i) has actual knowledge of the information;
> (ii) acts in deliberate ignorance of the truth or falsity of the information; or
> (iii) acts in reckless disregard of the truth or falsity of the information . . . .

31 U.S.C. § 3729(b)(1)(A). The "reckless disregard" prong was enacted in a 1986 amendment to the False Claims Act and, as the Sixth Circuit has recognized, was intended "to target that defendant who has 'buried his head in the sand' and failed to make some inquiry into the claim's validity." *U.S. ex rel. Williams v. Renal Care Grp., Inc.*, 696 F.3d 518, 530 (6th Cir. 2012) (citing S. Rep. 99-345, at 21, 1986 U.S.C.C.A.N. 5266, 5286).

The Consolidated Complaint asserts that Kroll personally "submitted or caused to be submitted over 15,000 false claims for specimen validity, genetic and psychological testing, acupuncture, and claims for testing, services and procedures for patients he could not have seen because he was out of the country, which amounts to at least $80 million in penalties, without factoring in treble damages for the amount of overpayment." (Doc. No. 65 ¶ 17.) It also asserts that Kroll was on the Board of Directors from August 2014 until CPS's dissolution (*id.* ¶ 86) and became Chief Medical Officer in 2016 (*id.* ¶ 88). His compensation included 100% of his net revenues collected, plus a percentage from the pool of "ancillary services revenues" to which non-owner providers contributed. (*Id.* ¶ 92.)

The Consolidated Complaint identifies policies implemented by CPS—through its Board of Directors and Owners, including Kroll—and asserts that the policies relating to UDT and other testing actively encouraged the submission of claims that the Owners knew was either non-reimbursable or not medically necessary. For instance, it alleges that defendant Davis directed CPS's third-party billing company in 2011 to "bill as 12 units every time" for UDT on Kroll's and the other Owners' patients. Kroll knew about this order for "routine and medically unnecessary testing" through a September 8, 2011 email that was copied to him. (*Id.* ¶ 122.) As of 2014, CPS had "weekly conference calls with providers to ensure that they were ordering and billing for the full panel of UDS, which included specimen validity testing." (*Id.* ¶ 129.) In September 2014,

CPS, with Kroll's approval, implemented a policy requiring providers to use a standing order that authorized a battery of tests for every new patient. (*Id.* ¶¶ 130, 133.) The Consolidated Complaint also describes the incentives offered to mid-level providers by CPS to conduct testing that CPS's Owners knew or should have known would result in medically unnecessary testing. It alleges that CPS's owners knew about defendant Smith's fraudulent conduct but failed to stop it or to notify the Government Health Care Programs of any overpayments.

In the section entitled "The Owners Knew or Should Have Known About the Unlawful Conduct," the Consolidated Complaint alleges that the Owners, including Kroll, were aware of the fraudulent conduct by other providers and by Davis, as evidenced by the facts that (1) they, too, submitted false claims for non-reimbursable or medically unnecessary testing; (2) they were aware of the ZPIC audit and the results of it; (3) they "turned a blind eye" to unlawful conduct for years, because they reaped the financial benefits associated with it; (4) they failed to take any steps to stop Davis from engaging in unlawful conduct and rewarded him with a compensation package based on the company's net profits; and (5) Kroll, as Chief Medical Officer, was directly involved in addressing the problems identified through the ZPIC audit and, as a member of the Compliance Committee, was privy to "countless emails about billing issues at CPS." (*Id.* ¶ 378.)

Based on these allegations and others, the Consolidated Complaint alleges that "the Owners knew or should have known about the extensive fraudulent conduct at CPS and failed to take any action to stop such conduct or to notify the [Government Health Care Programs] of the wrongdoing." (*Id.* ¶ 432.) As a result, the plaintiffs assert that the Owners, including Kroll, are "liable for all wrongful acts and/or omissions attributable to CPS." (*Id.* ¶ 433.)

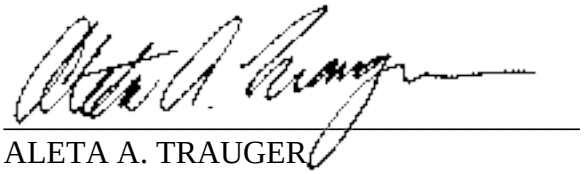
Construing the Consolidated Complaint in the light most favorable to the government, as the non-moving party, the court finds that it adequately alleges that Kroll caused the submission

of false claims by CPS and CPS's non-owner providers through the setting of CPS's policies and the implementation of financial incentives designed to induce the submission of false claims. The allegations are sufficient to permit a reasonable jury to find that Kroll was directly involved in a scheme to defraud the government, had knowledge of every part of the scheme, and either had actual knowledge of false claims being submitted by CPS or acted with reckless disregard of the likelihood that false claims were being submitted by CPS.

The motion to dismiss any claims on the grounds that the Consolidated Complaint attempts to hold Kroll vicariously liable for CPS's false claims will be denied, because the claims asserted against Kroll are not based on vicarious liability, and the facts supporting scienter are adequately pleaded.

V. CONCLUSION

For the reasons forth herein, the court will deny defendant Kroll's Partial Motion to Dismiss the Consolidated Complaint in Intervention (Doc. No. 96). An appropriate Order is filed herewith.



ALETA A. TRAUGER
United States District Judge